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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10 002,961	10/26/2001	Michael A. Lynes	883933.0070	4452

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EXAMINER

WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 06/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/002,961

Applicant(s)
Lynes et al.

Examiner
Randall Winston

Art Unit
1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) 8-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s): _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s): 4 and 5 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

Applicants' election with traverse of Group I, Claims 1-7 in Paper No. 8 is acknowledged. The traversal is on the grounds that the applicant argues examiner in setting forth the requirement states that "inventive groups are directed to different inventions which are not connected in design, operation and effect." The examiner has not used the classic terms "independent" or distinct" in this regard.

Applicants' argument is not found persuasive because, as the Examiner explained in the Restriction Requirement (Paper No.6), the inventive groups above are directed to different inventions (i.e., meaning "independent" or "distinct") which are not connected in design, operation, and/or effect. These distinct methods (Inventions II-III, methods, are distinguishable, each from the other, by each of applicants' methods has a different mode of operation (i.e. applicant Inventions II and III are different because Invention II, is drawn to a method of monitoring the translation motion of cells in response to extracellular chemical stimuli whereas Invention III is drawn to a method of determining the impact of a test substance on the ability of a chemical agent to affect the translational movement of cells) and these distinct compositions (Inventions I and IV are distinguishable, each from the other, by Invention I composition is drawn to a system for monitoring the effect of extracellular chemical stimuli on the translational motion of cells whereas Invention IV composition is drawn to system for the non-optical imaging of translational cell movement) are distinct since they are not disclosed as capable of use

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together, they have different modes of operation, they have different functions, and/or they have different effects. In addition, one would not have to practice the various methods and/or use the various compositions at the same time to practice just one method alone and/or one composition alone.

The restriction requirement is still deemed proper and is therefore made final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1(c) is rendered vague and indefinite for the broad term "chemical agent volume." One of ordinary skill in the art would not know how to interpret the metes and bounds of the broad term "chemical agent volume" Applicant may overcome this rejection by clearly defining this broad term within the claim language.

Claim 1(d) is rendered vague and indefinite for the broad term "biocompatible chemical gradient stabilizing medium." One of ordinary skill in the art would not know how to interpret the metes and bounds of the broad term "biocompatible chemical gradient stabilizing medium"

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Applicant may overcome this rejection by clearly defining this broad term within the claim language. (Does 'biocompatible chemical gradient stabilizing medium' means that cells migrate in and under an agarose environment?)

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 103(a) as being unpatentable over Giaever et al. (US 5,187,096) in view of Nelson et al. (Chemical Under Agarose etc, *Journal of Immunology*, Vol. 115, (1975), pp. 1650-1656).

Applicant claims a system for monitoring the effect of extracellular chemical stimuli on the translation motion of cells, the system comprising of an array of one or more cell containment volumes and an array of one or more chemical agent volumes (?), wherein the chemical agent volume is interspersed among the array of one or more cell containment volumes, wherein a biocompatible chemical gradient stabilizing medium (i.e under an agarose environment(?)) is in simultaneous diffusional contact with the arrays of cell containment volumes and chemical agent volumes, wherein the electrode are also (i.e. planar sensing electrodes of a particular surface area.

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counter electrodes and reference electrodes) distributed within the arrays of cell containment volumes and chemical agent volumes, and wherein the sensing electrode is coupled to a sensing device (i.e microprocessor) capable of measuring an electrical parameter of the sensing electrodes.

Giaever et al. teach a device for monitoring the activities of living cells in tissue culture using electronic means because Giaever's device comprises of a cell culture, wherein chemical agents are contained within the cell culture, wherein electronics (i.e. sensing device such as a amplifier/computer) are connected to arrays of electrodes contained within the cell culture whereas the electronic connected to the electrodes within the cell culture also containing chemical agents are used to monitor the activities of living cells in tissue culture (see, e.g. column 3 lines 36-48, claims, abstract, figure 1 and 3). Giaever et al., however, do not expressly teach all the different types of chemical agents contained within the cell culture, a biocompatible chemical gradient stabilizing medium that is in simultaneous diffusional contact with the arrays of cell containment volumes and chemical agent volumes and all the systems selected parts.

Nelson et al. beneficially teach that chemical agents under biocompatible chemical gradient stabilizing medium (i.e. under agarose) is being utilized to monitor the activities of cells.

One of ordinary skill in the art of preparing a system for monitoring the effect of extracellular chemical stimuli on the translational motion of cells would have been motivated to modify Giaever et al.'s device to include Nelson's teachings for an improved benefit of producing the instantly claimed device of monitoring the activities of cells. Moreover, it is mere

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matter of design choice to create a system which includes applicants' addition selected parts because it is notoriously well known in the art that conventional result-effective working conditions (e.g., applicants' selected additional parts such as counter electrodes and reference electrodes and the surface area of each of the one or more sensing electrodes) do not support the patentability of claimed subject matter, unless there is clear and sufficient evidence indicating such working condition(s) is/are critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" (see, e.g., MPEP 2144.05). Furthermore, the art recognizes functional or mechanical equivalency of a claimed compound/element with that of the prior art compound/element provides a *prima facie* case of obviousness for the skilled artisan to interchangeably substitute one equivalent for the other (see, e.g. MPEP 2144.06) within a system for monitoring the effect of extracellular chemical stimuli on the translational motion of cells (i.e. chemical agent substitution).

Accordingly, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group

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1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent

Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

row

A handwritten signature in black ink, consisting of a stylized 'C' followed by 'R. TATE'.

CHRISTOPHER R. TATE
PRIMARY EXAMINER